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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,522	11/28/2001	Cohava Gelber	3828-4000US1	9860

7590 06/25/2003

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EXAMINER	
HELMS, LARRY RONALD	
ART UNIT	PAPER NUMBER
1642	4

DATE MAILED: 06/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/995,522	GELBER, COHAVA	
	Examiner	Art Unit	
	Larry R. Helms	1642	

-- The MAILING DATE of this communication appears n the cover sheet with the c rresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 14-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-12 and 14-64* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, 30, and 35-39, drawn to a monoclonal antibody or binding fragment and pharmaceutical compositions comprising such, classified in class 530, subclass 388.85.

II. Claim 10, drawn to an anti-idiotypic monoclonal antibody, classified in class 530, subclass 387.2.

III. Claims 11-12, drawn to a cell line, classified in class 435, subclass 330.

IV. Claims 14-15, drawn to an isolated surface antigen of human myeloma cells with a molecular weight of about 78-120 kDa, classified in class 530, subclass 300, for example.

V. Claims 16-17, drawn to an isolated surface antigen of human ovarian cancer cells with a molecular weight of 76-213 kDa, classified in class 530, subclass 350, for example.

VI. Claims 18, drawn to a method for inhibiting or killing myeloma tumor cells or ovarian cancer tumor cells in a patient, classified in class 424, subclass 156.1.

VII. Claims 19-20, drawn to a method for inhibiting or killing tumor cells or ovarian cancer tumor cells in a patient with an antibody cytotoxic conjugate, classified in class 424, subclass 393.1.

VIII. Claims 21-24, drawn to a method for removing myeloma cells from a isolated cellular sample using a solid matrix, classified in class 530, subclass 412.

IX. Claims 25-29, drawn to a method for inhibiting or killing myeloma cells in an isolated cellular sample, classified in class 424, subclass 391.1.

X. Claims 31-32, drawn to a method for localizing myeloma or ovarian cancer cells in a patient , classified in class 424, subclass 391.1.

XI. Claims 33, 40-50, 57-64, drawn to a method for detecting the presence and extent of ovarian cancer in a patient, classified in class 435, subclass 7.92, for example.

XII. Claims 34, 51-56, drawn to a method for monitoring the effectiveness of therapy for ovarian cancer, classified in class 435, subclass 7.1, for example.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I-V represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. The antibody of Group I, the anti-idiotypic antibody of Group II, The hybridoma cell line of

Group III, the antigen of myeloma cells of Group IV, and the antigen of human ovarian cancer cells of Group V are all structurally and physically different from each other. The antigens can be made by translation of the mRNA, the antibody can be made by immunization, and the hybridoma cell line is made by fusion techniques. The anti-idiotypic antibody of Group II and the antibody of Group I are distinct in having different structural and functional characteristics. The antibody binds an antigen from human myeloma cells or ovarian cells and the anti-idiotypic antibody bind the antibody. The anti-idiotypic antibody would comprise different CDRs than the CDRs in the antibody. The antigens of Groups IV and V are distinct in that each is derived from a specific cell, for example the antigen of Group IV is from human myeloma cells and the antigen of Group V is from ovarian cancer cells. In addition, the antigens are distinct in having different structure and functional characteristics, for example different molecular weights on SDS PAGE. Furthermore, the antigen polypeptides can be used for methods of treatment and the antibody can be used to immunopurify the antigen, for example. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus the inventions I-V are patentably distinct.

The methods of Inventions VI-XII differ in the method objectives, method steps and parameters and in the reagents used. Invention VI recites a method for inhibiting or killing myeloma tumor cells or ovarian cancer tumor cells in a patient with an antibody; Invention VII recites a method for inhibiting or killing myeloma tumor cells or ovarian cancer tumor cells in a patient with an antibody cytotoxic conjugate; Invention VIII

recites a method for removing myeloma cells from an isolated cellular sample using a solid matrix; Invention IX recite a method for inhibiting or killing myeloma cells in a isolated cellular sample with a cytotoxic conjugate of an antibody; Invention X recites a method for localizing myeloma or ovarian cancer cells in a patient comprising administering an antibody with a detectable label; Invention XI recites a method for detecting the presence and extent of ovarian cancer in a patient and correlating the quantity of antigen with the presence and extent of ovarian cancer cells; and Invention XII recites a method for monitoring the effectiveness of therapy for ovarian cancer comprising measuring the changes in the level of antigen and correlating the change in level with the effectiveness of therapy. The examination of all groups would require different searches in the U.S. PATENT shoes and the scientific literature and would require the consideration of different patentability issues. Thus Inventions VI-XII are separate and distinct in having different method objectives, method steps and parameters and in the reagents used and are patentably distinct.

Inventions I and VI-XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group I can be used in a materially different method such as immunoprecipitation of the antigen in addition to the methods of Groups VI-XII.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different classifications, restriction for examination purposes as indicated is proper.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

6. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

Respectfully,

Larry R. Helms Ph.D.